

## **Remarks**

Applicant has carefully studied the Office Action, mailed November 12, 2008 (hereinafter “the Action”); Applicant believes the amendments appearing above and these explanatory remarks are fully responsive to the Action. Accordingly, this important patent application is now in condition for allowance.

## **Status of the Claims**

Claims 19-20, 23-24 and 26 are pending and under consideration. Claims 1-18, 21-22 and 5 have been cancelled by virtue of the amendments above. Claim 26 is new. All amendments appearing above are supported by the original specification and figures. Applicant thanks the Office for entering the remarks filed May 16, 2008, as well the Office’s consideration thereof.

All claims depend, directly or indirectly, from claim 19. Therefore, if claim 19 is found to be non-obvious under 35 U.S.C. §103(a), then all claims which depend therefrom are non-obvious as a matter of law. (*See e.g.* M.P.E.P. §2143.03). Accordingly, and without conceding the propriety of any asserted rejection, Applicant shall forego a detailed analysis of any claim depending from an independent claim shown to be nonobvious. The absence of additional patentability arguments should not be construed as either a disclaimer of such arguments or that such arguments are not believed to be meritorious.

## **Claim Objections**

Claims 21 and 22 have been cancelled, thereby rendering the objects thereto moot.

## **Claim Rejections - 35 U.S.C. §103(a)**

Claims 19-25 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Garattini *et al.* (Current Opinion in Pharmacology) (“Garattini”) in view of Bernardi *et al.* (“Bernardi”). Applicant respectfully requests favorable reconsideration and withdrawal of the rejection on these grounds as the proposed combination does not teach all the elements of claim 19 (as amended).

Independent claim 19 recites, inter alia, a method of inducing apoptosis in imatinib mesylate refractory cancer cells. If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim. M.P.E.P. §2111.02.<sup>1</sup> A preamble is also to be construed as a claim element when it is not merely a statement of effect that may or may not be desired or appreciated, but rather is a statement of the intentional purpose for which the method must be performed. M.P.E.P. §2111.02(II).<sup>2</sup> Statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, *manipulative difference*) between the claimed invention and the prior art. If so, the recitation serves as a claim element. *Id.* (emphasis added).<sup>3</sup> Lastly, clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention. *Id.*<sup>4</sup>

The selection of imatinib mesylate refractory cells is not merely an effect that may or may not be appreciated but is the intentional purpose for which the method must be performed. Therefore, and in combination with Applicant's clear reliance on the preamble as a claim element, Applicant submits that the recitation of a method of inducing apoptosis in imatinib mesylate refractory cancer cells is to be construed as a claim limitation. Furthermore, Applicant respectfully submits that neither reference, alone nor in combination, disclose at least a method of inducing apoptosis in imatinib mesylate refractory cancer cells as recited in claim 19.

Having established that the preamble must be construed as a claim element, the Office must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup*

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<sup>1</sup> Citing *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003) (In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose.).

<sup>2</sup> Citing *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158.

<sup>3</sup> Citing *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

<sup>4</sup> Citing *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785.

Intern. Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Section 2143.03 of the MPEP requires the “consideration” of every claim feature in an obviousness determination. To render claim 19 unpatentable, however, the Action must do more than merely “consider” each and every feature for this claim. Instead, the asserted combination must also teach or suggest *each and every claim feature*. See In re Royka, (emphasis added).<sup>5</sup>

Indeed, as the Board of Patent Appeal and Interferences has recently confirmed, a proper obviousness determination requires that an Examiner make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” See In re Wada and Murphy, Appeal 2007-3733, *citing In re Ochiai*, (emphasis in original). Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ... ascertaining the differences between *the claimed invention* and the prior art. Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) (emphasis added).

Neither Garattini nor Bernadi discuss the use of a histone deacetylase inhibitor to make imatinib mesylate refractory cells more susceptible to the effects of imatinib mesylate. Moreover, Garattani expressly teaches away from inducing apoptosis but instead teaches the use of compounds for inducing cytodifferentiation in cancer cells. Cytodifferentiation seeks to force neoplastic cells to acquire a phenotype that is similar to that of their corresponding terminally differentiated normal counterparts<sup>6</sup> in an attempt to avoid the “serious side effects” caused by cytotoxic chemotherapy.<sup>7</sup> If the proposed modification or combination would change the principle of operation of the prior art, as is the case here, then the teachings of the references are not sufficient to render the claims obvious. M.P.E.P. §2143.01(V).

For these reasons at least, Applicant requests the reconsideration and withdrawal of the rejection of claim 19 under 35 U.S.C. §103(a). Likewise, all remaining claims depend from claim 19 and are also nonobvious under 35 U.S.C. §103(a).

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<sup>5</sup> To establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art.

<sup>6</sup> Garattini, Page 358, Col. 2

<sup>7</sup> *Id.*, see Abstract

**Conclusion**

Entry of a Notice of Allowance is solicited. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

**SMITH & HOPEN**

/thomas e toner/

By:\_\_\_\_\_

Dated: February 6, 2009

Thomas E Toner

Reg. No. 57,422

180 Pine Avenue North

Oldsmar, Florida 34677

Attorneys for Applicant

*CERTIFICATE OF ELECTRONIC TRANSMISSION*

**(37 C.F.R. 2.190 (b))**

I HEREBY CERTIFY that this correspondence is being electronically transmitted to the Patent and Trademark Office through EFS Web on February 6, 2009.

/lauren reeves/

Date: February 6, 2009

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Lauren Reeves